

## REMARKS

### **I. Preliminary Comments**

The independent claims have all been amended to recite that the proportion of resistant starch is at least 15% of the total carbohydrate content or 20% of the total starch content which amendment is supported at page 9, lines 9 and 14 of the disclosure. The inventors have shown that consumption of a diet high in resistant starch and unsaturated fats or lipids results in desirable effects on carbohydrate and fat metabolism. In particular, the inventors have shown beneficial results resulting from diets which replace at least 15% of an individual's daily carbohydrate intake with amylase resistant starch and at least 10% of the individual's saturated fat intake with unsaturated fat.

Applicants note, with gratitude that the previous rejections under Laughlin in view of Watanabe, U.S. Patent 5,300,311 and Garg, American Journal of Clinical Nutrition, 1998 have now been withdrawn.

### **II. Outstanding Rejections**

Claims 1-10 and 26-33 are rejected under 35 U.S.C. § 112 (second paragraph) as being indefinite.

Claims 1-5, 7-10, 26-28 and 30-33 are rejected under 35 U.S.C. §102(b) as being anticipated by Brown et al., WO 96/08261 (which corresponds to U.S. 6,060,050).

Claims 6 and 29 relating to treatment of subjects for obesity are rejected under 35 U.S.C. §103(a) as being obvious over the disclosure of Klor et al., U.S. Patent 5,886,037 in view of Wibert et al., U.S. Patent 5,776,887 and further in view of Seib et al., U.S. Patent 5,855,946.

### **III. Patentability Arguments**

#### **A. The Rejection Under 35 U.S.C. §112 (second paragraph) Should Be Withdrawn.**

The rejection on the basis that the claims are indefinite should be withdrawn because those of ordinary skill would understand how to consistently determine grams and percentages of resistant starch content as recited by the claims. Those of ordinary skill in the art would have measured resistant starch levels by practice of the method of the McCleary method described in of McCleary, Proc. 42<sup>nd</sup> RACI Cereal Chem. Conf. Christchurch, NZ Ed. VJ Humphrey-Taylor pp 304-312 (1992). The McCleary method was known since 1992 and was approved by the Association of Official Analytical Chemists [AOAC] as the only approved method for determining the amount of resistant starch.

Those of ordinary skill would have recognized from Applicants' specification that the McCleary method be used to determine resistant starch levels. First, Applicants' specification teaches at para. 0035:

“[0035] As used in this specification, the term "resistant starch" includes those forms defined as RS1, RS2, RS3 and RS4 as defined in Brown, McNaught and Moloney (1995) Food Australia 47:272-275.”

Brown, et al., Food Australia, (1995) in turn taught that “resistant starch” was defined as “the sum of starch and products of starch degradation not absorbed in the small intestine of healthy individuals” (pg. 272, col. 2 lines 8-14). Brown then cited Prosky et al., J. Assoc, Off. Anal. Chem. 71(5):1017 (1988) as providing “the officially accepted method of the Association of Analytical Chemists” for detecting resistant starch.

Applicants' specification also refers to Goodman Fielder WO 94/14342 and WO 94/03049 which in turn instruct use of the McCleary method. WO 94/03048 describes the analysis by the method of McCleary, Proc. 42<sup>nd</sup> RACI Cereal Chem. Conf. Christchurch, NZ Ed. VJ Humphrey-Taylor pp 304-312 (1992). While WO 94/14342, (which corresponds to Brown U.S. 6,303,174) refers to the analytical methods of both Muir et al. and McCleary et al., it is noted that the McCleary and Muir methods give results which are within the accepted experimental error and thus are considered to be the same.

In addition, the prior art as reflected in numerous Brown et al., Goodman Fielder Limited issued US patents took a consistent approach to the measurement of resistant starch. Specifically, US 5,714,600 (July 31, 1992 priority) discloses the use of the McCleary method at col. 8 lines 25-27; and US 6,060,050 (September 16, 1994 priority) corresponding to the Brown WO 96/08261 reference applied by the Examiner also relies upon the use of the McCleary method at col. 6, table 3 to measure resistant starch levels.

**B. The Rejection Under 35 U.S.C. §102(b)  
Over Brown et al., WO 96/08261 Should be Withdrawn.**

The rejection of claims 1-5, 7-10, 26-28 and 30-33 under 35 U.S.C. § 102(b), over Brown WO 96/08261 should be withdrawn as Brown does not disclose or suggest a method for regulating carbohydrate and fat metabolism comprising replacing at least 15% of the individual's daily carbohydrate intake with resistant starch and at least 10% of the individual's saturated fat intake with unsaturated fat. Alternatively, Brown fails to disclose replacing at least 20% of the individual's starch intake with resistant starch and at least 10% of the individual's fat intake with unsaturated fat.

While Table 9 of Brown discloses that the total amount of amylase resistant starch in the composition is about 90 grams (i.e., about 9% of the whole experimental diet, or about

11% of the total carbohydrate) applicants have now amended all their independent claims to recite a minimum resistant starch proportion of 15% of total carbohydrate and/or 20% of total starch thus avoiding anticipation by the disclosure of Brown. Accordingly, the anticipation rejection over Brown should be withdrawn.

Moreover, no new rejection should be entered under 35 U.S.C. §103 over Brown because it fails to render the subject matter of the amended claims obvious. While Brown Table 9 discloses the use of unsaturated safflower oil the reference also discloses the use of saturated fats including hydrogenated vegetable oils and mixtures of hydrogenated and non-hydrogenated vegetable oils, such as palm oil, for a method of extrusion to produce a granular product. As such there is no instruction to select unsaturated fats instead of saturated fats of use in the manner of the invention and the extrusion process teaches away from the present invention.

Specifically, Brown teaches only that a combination of resistant starch and probiotic microorganisms can promote the growth of microorganisms in the large bowel (i.e. resistant starch functions only as a carrier and a growth medium for the microorganisms). Thus, Brown does not disclose or teach that a combination of resistant starch and unsaturated fats when used as a replacement for a percentage of a daily intake of carbohydrates can result in the regulation of carbohydrate and fat metabolism resulting in a reduction in fat accumulation, lower plasma leptin concentration and reduced glucose and/or insulin levels.

Moreover, there is no suggestion that the invention described in Brown can promote a reduction in obesity and lead to enhanced sports performance. While applicants do not dispute that a pig would be expected to eat at least 113g of the composition as described in Table 9 of Brown, that disclosure does not teach that the feeding of the composition to pigs would lead to the regulation of fat metabolism and reduction in fat accumulation. Moreover,

the person skilled-in-the art would not associate the feeding of the composition in Table 9 to pigs with any form of fat reduction. Instead, a person skilled-in-the-art it would assume that such feeding would promote an increase in body weight.

For these reasons the anticipation rejection under 35 U.S.C. §102 over Brown should be withdrawn and no new obviousness rejection under 35 U.S.C. §103 over Brown should be entered.

**C. The Rejection Under 35 U.S.C. §103(a) Over Klor et al.  
In View of Wibert et al., and Seib et al. Should be Withdrawn.**

The rejection of claims 6 and 29 directed to the treatment of obesity under 35 U.S.C. §103(a) over of Klor et al., U.S. Patent 5,886,037 in view of Wibert et al., U.S. Patent 5,776,882 and further in view of Seib et al. should be withdrawn. While Klor is directed to the treatment of obesity and diabetes by the modification of fat intake combined with a relatively low content of carbohydrates (see col. 3, lines 31-33) it fails to teach that the total carbohydrate and fat levels in compositions could remain unchanged, or that replacement of amounts of carbohydrate with equal amounts of resistant starch, and amounts of saturated fat with equal amounts unsaturated fat, could provide a method for regulating carbohydrate and fat metabolism as is described in Applicants invention.

Moreover, there remains confusion within Klor itself as to what it teaches because its Abstract refers to large amounts of “polyunsaturated chain fatty acids caprylic and capric acid.” It is unclear whether Klor teaches the use of saturated or unsaturated fatty acids because caprylic acid and capric acids are actually saturated fatty acids. Accordingly, while Klor et al. discloses a composition comprising relatively low amounts of unsaturated fats, it emphasizes the benefits of a composition having 55-95% medium chain saturated fatty acids.

In addition, Klor fails to teach the substitution of resistant starch for other types of starches and carbohydrates. Specifically, the reference in the Office Action to the composition at Column 5 of Klor (see "Example") comprising 46 wt % carbohydrate, 20 wt % protein, and 29.6 wt % fat refers to maltodextrin and thus teaches away from the use of a resistant starch in such a composition.

The Wibert et al. reference, which does describe a high amylose starch containing composition, fails to make up for the deficiencies of Klor because it fails to suggest the use of that resistant starch in the amounts or manner of the invention. While the addition of carbohydrates, such as starch, to Klor's composition would not be unusual at the time of applicant's invention, the addition of such carbohydrates would be at the levels specified in Klor and there is no teaching in Klor that the level of resistant starch in Novelose could be used to replace an equal amount of non-resistant starch. Further, there is no teaching that such replacement, in combination with replacement of saturated fat by an equal amount of unsaturated fat, would lead to applicant's method for regulating carbohydrate and fat metabolism.

Moreover, Wibert suggests, at Column 3 from line 60 onwards, that the fat component can be any lipid or fat known in the art to be suitable for use in nutritional compositions including saturated fats. At lines 65 onwards Wibert teaches that the typical fats used include fats such as, for example, milk fats, safflower oil, egg yolk lipid, palm oil and fish oil. Medium chain triglycerides (mct) and esters of fatty acids can also be used, wherein the fatty acids include for example caprylic acid and capric acid, (saturated fatty acids). Thus, Wibert gives no indication with regard to the types of fats that should be consumed and would not have motivated one to replace the saturated fat in Klor with unsaturated fat.

Moreover, the person of ordinary skill in the art would not combine the teachings of Klor and Wibert in any manner, much less to arrive at the composition of the invention, because the two references have an entirely different focus. On the one hand, Klor is directed to a nutritional composition having very large amount of fats most of which are medium chain fatty acids, i.e., saturated fats. Carbohydrates are optional according to the Klor composition. Klor gives no motivation to explore the use of different resistant starches, much less to include a certain amount of resistant starch to replace other forms of carbohydrate.

On the other hand, Wibert is directed to a composition which mostly comprises carbohydrate. However, no specific amount of amylase resistant starch is recommended and there is no motivation to choose any particular fat, whether saturated or unsaturated.

Finally, Seib teaches that Novelose high amylose starch comprises amylase resistant starch but does not teach one to alter the composition of Wibert in a manner to arrive at Applicants' invention.

For these reasons the rejection based on the combination of Klor and Wilbert in further combination with Seib should be withdrawn.

**CONCLUSION**

For all of the foregoing reasons, the rejection should now be withdrawn and a notice of allowance of all pending claims is respectfully solicited. Should the Examiner wish to discuss any issues of form or substance in order to expedite allowance of the pending application, she is invited to contact the undersigned attorney at the number indicated below.

Respectfully submitted,

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